

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re Bair Hugger Forced Air Warming  
Products Liability Litigation

MDL No. 15-2666 (JNE/FLN)

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This Document Relates to All Actions

**PLAINTIFFS' REPLY IN SUPPORT  
OF THEIR MOTION TO EXCLUDE  
DEFENDANTS' EXPERT JIM HO**

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Defendants' response concedes that Dr. Ho is being offered for two purposes<sup>1</sup>:

- 1) to dispute that particles correlate with bioburden
- 2) to opine on the safety performance of the Bair Hugger filter

With respect to the first topic, Dr. Ho should be excluded because his literature review methodology was abjectly lacking, a flaw which cannot now be rehabilitated *ex post facto* by attorney argument. With respect to the second topic, Dr. Ho should be excluded because his filter opinion was based on a factually incorrect premise, a flaw entirely ignored by Defendants' response. Because of this flaw, Dr. Ho admitted he could only speak to engineering function, not safety. Finally, Defendants shrug off Dr. Ho's naked advocacy, but the transcript shows that he approached this case and his opinions with a lack of objectivity.

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<sup>1</sup> Plaintiffs' Motion, Section III, argued that Dr. Ho is unqualified to give opinions on studies regarding Bair Hugger safety generally. Defendants offered no response to this argument, and thus it is assumed to be agreed and will not be addressed in this reply.

## ARGUMENT

### **I. Attorney Argument does not Excuse Dr. Ho's Slipshod Literature Review on the Relationship Between Particles and Bacteria.**

The parties' briefing discusses a host of studies which researched the correlation between particles and bacteria, but very few of them were actually reviewed or considered by Dr. Ho in coming to his opinions. Defendants cannot escape the fact that Dr. Ho did not do anything close to the kind of literature review which would be accepted by similar experts in his field outside litigation.

Defendants claim "Plaintiffs neglect to advise the Court of key articles that refute their 'particles = bacteria = infections' formulation – notably Landrin (2005), Cristina (2012), and Birgand (2015)." (Doc. 877, p. 5). However, Plaintiffs certainly did discuss Landrin (2005), and in fact quoted from other authors discussing its aberrant results and problematic design. Plaintiffs noted that Dr. Ho could not explain why he relied on this study in the face of so many others he had not reviewed.

For example, Defendants claim Plaintiffs did not inform the Court of the study by Birgand et al.,<sup>2</sup> but Dr. Ho did not review the Birgand study or factor it into his opinions at all. Indeed, the citation of the Birgand study by Defendants' counsel only underscores the incomplete nature of his literature review, because it was not included by Dr. Ho in his materials. Similarly, Defendants also reference a literature review article by Mora et

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<sup>2</sup> Birgand G., et al., "Air contamination for predicting wound contamination in clean surgery: A large multicenter study" 43 *Am. J. of Infection Control* 516 (2015).

al.<sup>3</sup> However, much like the Birgand paper, Dr. Ho did not review the Mora article or rely on it in any way in coming to his opinions.

With respect to the article by Cristina et al (2012), this study is not applicable to the issue under dispute. In the Cristina study, “[m]easurements were performed when instruments released surgical smoke, for example an ultrasonic scalpel.”<sup>4</sup> The authors were measuring these particles for bacterial threat.<sup>5</sup> The authors were only measuring specific particle ranges associated with surgical tool smoke, and thus “one of the limitations of the present research is that only two particulate fractions were studied.”<sup>6</sup> The authors specifically warned that their study cannot be used to contradict “a correlation between the number of particles/m<sup>3</sup> and CFU/m<sup>3</sup>,” which they noted “has been reported by Stocks et al.”<sup>7</sup>

Defendants completely dismiss the study by Stocks et al, even though Russell Olmstead, 3M’s own consultant retained to analyze clinical microbiology issues, enthusiastically supported the Stocks’ findings. Defendants claim that Olmstead’s “endorsement of the Stocks study carries little weight because he lacks Dr. Ho’s expertise in aerobiology.” (Doc. 877, p. 6-7). However, this is false. Olmstead shares the identical area of expertise, and he stated in his endorsement that he has conducted and published

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<sup>3</sup> Mora M. et al., “Microorganisms in Confined Habitats: Microbial Monitoring and Control of Intensive Care Units, Operating Rooms, Cleanrooms and the International Space Station” 7 *Frontiers in Microbiology* 1, 6 (2016).

<sup>4</sup> See Ho Rpt., 14

<sup>5</sup> Cristina ML, Spagnolo AM, Sartini M, Panatto D, Gasparini R, Orlando P, Ottria G, Perdelli F. 2012. Can Particulate Air Sampling Predict Microbial Load in Operating Theatres for Arthroplasty? *PLoS One* 7:e52809.

<sup>6</sup> The paper was printed in a publication called Plos One, created by an entity known as the Public Library of Science (PLOS). Plos One is a pay-to-publish open access journal. The study can be viewed in its entirety at: <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0052809>.

<sup>7</sup> *Id.*

on the type of testing conducted by Dr. Stocks' team. Defendants next claim that "there is no indication from Mr. Olmstead's cursory email that he reviewed the Stocks data as closely as Dr. Ho did." (Doc. 877, p. 9). However, Dr. Ho's opinions are not based on any kind of exhaustive examination. Instead, Dr. Ho said that a qualified person "right away would say that this is scattered data all over the map."<sup>8</sup> Dr. Ho claimed that "[a]nybody who has done particle counting would immediately recognize" that the Stocks findings were false,<sup>9</sup> and they would know that it was "very bad" data.<sup>10</sup> In their response, Defendants even acknowledge that Dr. Ho's criticism of the study arises from "[a] glance at Fig. 1 of the Stocks article." (Doc. 877, p. 8).

Defendants' counsel also attempt to criticize the findings of the study by Darouiche et al, but none of these criticisms come from Dr. Ho, who never reviewed the study in preparing his report of in advance of his deposition.<sup>11</sup> Most of Defendants' criticism concern a relationship with Nimbic, a party unrelated to this suit. To the extent the conflict of interest is relevant to a discussion of the study, it is equally relevant to the reliability of Dr. Ho's literature review methodology, because Dr. Ho never even considered the study or generated his own reasons to dismiss it. Dr. Ho agreed that when he dismissed the study during his deposition, he did not know Dr. Darouiche, was not aware of any conflicts, and did not "know what his motivations were in doing this

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<sup>8</sup> See Ho Dep. at 174:17-21.

<sup>9</sup> *Id.* at 186:22-25.

<sup>10</sup> *Id.* at 175:4-8.

<sup>11</sup> *Id.* at 201:5-8.

study.”<sup>12</sup> Nor, apparently, was Dr. Ho aware that Defendants’ other experts agree that Dr. Darouiche is an expert, and that his study is authoritative.

Defendants have likewise provided the Court with nothing but attorney argument concerning the studies by Raval et al and Zheng et al. These attorney arguments may be perfectly appropriate to raise in the cross-examination of Plaintiffs’ experts, but again, none of it comes from Dr. Ho, and none of it speaks to the reliability of Dr. Ho’s methodology because he *never reviewed the studies* at all.<sup>13</sup> Finally, Defendants response completely ignores the study by Seal and Clark, one of the few studies Dr. Ho actually did review, but dismissed for no reliable reason.<sup>14</sup>

Dr. Ho has no reliable basis to conclude that particles cannot act as a representational surrogate for bioburden given that he did not review and account for the immense weight of contrary evidence. Under the application of a reasonable methodology, Dr. Ho would have been aware of these numerous studies and would have explained why he could reliably ignore their consensus in coming to his opinions. A reliable scientist applying an appropriate methodology would not require his attorneys to do this for him. While experts need not review every applicable study, an expert cannot simply ignore the great weight of published authority on the subject matter. *Huggins v. Stryker Corp.*, 932 F.Supp.2d 972, 993–94 (D.Minn. 2013).

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<sup>12</sup> *Id.* at 214:1 to 215:7.

<sup>13</sup> *Id.* at 188:20-22.

<sup>14</sup> Ho Report, p. 34.

## **II. Defendants Ignore Both the False Premise Underlying Dr. Ho's Filter Opinions and his Explicit Limitation on his Testimony.**

Defendants contend that Dr. Ho “is well qualified to review and comment on the literature assessing the effectiveness of MERV 14 filtration.” (Doc. 877, p. 15). However, Defendants offer no real support for this contention. Dr. Ho's opinions are not based on any understanding of the Plaintiffs' theory of defect, and he lacks knowledge of the basic allegations and medical disputes of the case. He admits he has no “understanding of how the plaintiffs believe the Bair Hugger caused their infections,”<sup>15</sup> nor was he able to describe “what a peri-prosthetic joint infection is.”<sup>16</sup> Dr. Ho is not a medical doctor, nor is he an engineer, biomedical or otherwise. He testified that he is not an expert in evaluating clinical outcomes,<sup>17</sup> orthopedic surgery,<sup>18</sup> or operating rooms.<sup>19</sup> Dr. Ho also testified that he did not “have any expertise on the levels of bioburden within an operating room.”<sup>20</sup> Nonetheless, Defendants intend to offer Dr. Ho as an expert on the clinical adequacy of filtration, and argue Dr. Ho “may be more qualified than anyone else in the world to address issues of airborne bacteria”. (Resp. at 1)

Even if Dr. Ho were qualified, Defendants ignore the supposed basis for his opinion, which is that he believes that filter accomplishes the “removal of all bacterial particles sized within .3 to 1 micron.”<sup>21</sup> During his deposition, Dr. Ho was shown the confidential testing conducted by 3M to provide an “assessment of the filter efficiency on

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<sup>15</sup> *Id.* at 27:4-7.

<sup>16</sup> *Id.* at 23:3-5.

<sup>17</sup> *Id.* at 17:11.

<sup>18</sup> *Id.* at 22:3.

<sup>19</sup> *Id.* at 21:8.

<sup>20</sup> *Id.* at 21:11.

<sup>21</sup> *Id.* at 57:22-23; *see also* Ho Rpt. at p. 25.

the Bair Hugger system.”<sup>22</sup> The results showed that the filter is not capable of removing all bacterial particles up to 1 micron, and in fact allowed as much as 25% of those particles to pass through.<sup>23</sup> Dr. Ho was forced to admit that the filter “does not meet the standard in which [he] expressed in [his] report.”<sup>24</sup> An opinion cannot be reliable when it is based on a factually incorrect premise.

Moreover, Defendants misunderstand the extent to which Dr. Ho disclaimed the ability to opine about the filter’s performance in terms of bacterial contamination. Defendants admit that Dr. Ho could not state an opinion “on matters of patient safety,” but they nonetheless claim “Dr. Ho opines that a MERV 14 filter effectively controls bacteria.” (Doc. 877, p. 15). However, Dr. Ho did *not* opine that the filter “effectively controls bacteria.” Rather, Dr. Ho testified that “I can say that the filter selected is adequate for the performance of the instrument.”<sup>25</sup> Dr. Ho specifically delineated between mechanical function and patient safety “because safety is a whole different issue.”<sup>26</sup> Dr. Ho flatly admitted he could not conclude that the filter effectively controls bacteria, nor could he say the filter is “sufficient to provide reasonable assurance that a patient will not suffer peri-prosthetic joint infection.”<sup>27</sup>

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<sup>22</sup> *Id.* at 63:2 to 63:9.

<sup>23</sup> *Id.* at 66:18 to 67:13.

<sup>24</sup> *Id.* 67:15-17

<sup>25</sup> *Id.* at 73:1-8.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at 74:25 to 75:5.

### **III. Defendants Cannot Defend Dr. Ho's Advocacy or Deny its Effect on his Testimony.**

Defendants claim that Dr. Ho's strange behavior throughout his deposition reflects his lack of understanding of American-style cross-examination. To the contrary, any fair reading of the transcript shows that it is the purpose and role of an expert witness that Dr. Ho has misunderstood. Defendants can offer no defense for an expert who openly admits that he is "not going to criticize authors that are favorable of 3M."<sup>28</sup> His belief that he serves an advocate has permeated all his opinions and undermined his methodology. Accordingly, his testimony must be excluded.

### **CONCLUSION**

Dr. Ho's testimony will not be helpful to the jury. His opinion concerning the relationship between particles and bioburden suffers from an unreliable methodology, and it is contradicted by an immense weight of findings he did not consider. His opinion regarding the filter is based on a factually incorrect premise, and by his own admission must be limited to engineering function rather than safety. Finally, Dr. Ho's opinions were formed as an advocate, not an objective witness. He should be excluded from testifying.

Respectfully submitted,

Dated: October 17, 2017

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<sup>28</sup> *Id.* at 295:20 to 296:6.



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